

REMARKS

Reconsideration and allowance of the subject application are respectfully requested.

Claims 1-27 are pending in this application. Claims 1-12 and 14-19 have been withdrawn from consideration as being drawn to a non-elected invention. Claim 20 has been amended for clarity. Claims 24-27 are newly added.

The applicants respectfully traverse the rejection of claims 13 and 21-23 under 35 USC 103(a) over USP 5,849,527 (US '527) in view of USP 5,663,315 (US '315). The cited references do not make the presently claimed invention to be obvious.

The Office Action states that US '527 teaches diagnosis of a disease which comprises measuring CF6 levels in body fluids by using an anti-CF6 antibody. However, the US '527 does not refer to CF6, but to HMF6 which is designated as a human mitochondrial F6 subunit. (please see to column 2, lines 20-24, and the Abstract.)

A person of ordinary skill in the art would understand that HMF6 has an amino acid sequence shown in SEQ ID NO:1 which is clearly different from coupling factor 6 (CF6) of the present invention or F6 in US '527. The amino acid sequence of factor 6 (CF6) is designated as SEQ ID NO: 3 (GI 183786) and shown in Figure 2. (please see Figure 2 and column 2, lines 56-61 of US '527.)

Thus, CF6 of the presently claimed invention differs in primary structure from HMF6 of US '527 and therefore an anti-HMF6 antibody produced as by US '527

would be understood by a person of ordinary skill in the art as being different from the anti-CF6 antibody of the presently claimed invention.

US '527 teaches a method of detecting HMF6 in human body fluids or extracts of cells or tissues with use of the anti-HMF6 antibody and a label. (please see column 22, lines 36-41). However, according to the explanation in the Office Action, US '527 does not teach or confirm the presence of HMF6 in blood. Thus, it would be understood by a person of ordinary skill in the art that US '527 does not teach the presence of CF6 in blood.

As explained in the specification of the present application, prior to the present invention it was known that CF6 is present in the mitochondrial inner membrane, and it was unknown as to whether CF6 is present in blood. This is similarly disclosed in US '527 at column 1, lines 54-58, wherein F6 is a small 76 amino acid coupling factor that, like most mitochondrial proteins, is the product of a nuclear gene that is imported into the mitochondria. This means that F6 is present in mitochondria in cells. Thus, US '527 confirmed the presence of HMF6 in cells or body fluid and did not try to detect the presence of HMF6 in blood.

The inventors of the present invention found that CF6 is present in blood, that the concentration of CF6 in blood is associated with certain diseases and that CF6 in blood affects aggravation or improvement of those diseases.

In view of the reasons stated above, the applicants submit that US '527 teaches the presence of HMF6 in cells(mitochondria) or in body fluid but does not teach or suggest the presence of HMF6 in blood.

The Office Action states that US '315 teaches diagnosing a disease state by detecting a protein in one of body fluids of human and that the combination of US '315 and US '527 makes the claimed invention obvious.

However, the applicants respectfully assert that a person of ordinary skill in the art would find no suggestion or motivation to combine the secondary reference, US '315 with the primary reference, US '527. In support of this, please consider the following:

(a) The US '315 reference refers to the term "bodily fluid", which includes blood, serum or urine. However, as explained above, a person of ordinary skill in the art would not have tried to detect HMF6 in blood, because US '527 does not teach that HMF6 may be present in blood.

(b) To the present inventors' knowledge, they first and newly found that CF6 is present in blood (see present specification) and therefore, the skilled person in the art can not have any motivation to detect CF6 in blood. In addition, US '527 teaches HMF6 which is different from CF6 of the present invention.

Thus, those of ordinary skill in the art would not consider the combination of US '315 with US '527. The applicants submit that the combination of references is not tenable and should accordingly be withdrawn.

Even if the combination of references were considered, then such combination would not make the presently claimed invention obvious for the several reasons discussed above.

The applicants submit that the presently claimed invention is nowhere disclosed, suggested or made obvious by the teachings of the prior art. The